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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,101	10/09/2003	Daniel F. Justin	ZIM0403	9213
<div>7590 07/07/2009</div> <div>John F. Hoffman, Esq. BAKER & DANIELS LLP Suite 800 111 East Wayne Street Fort Wayne, IN 46802</div> <div>EXAMINER NEGRELLI, CHRISTINA L</div> <div>ART UNIT 3733</div> <div>PAPER NUMBER</div> <div>MAIL DATE 07/07/2009</div> <div>DELIVERY MODE PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/682,101

Applicant(s)

JUSTIN ET AL.

Examiner

CHRISTINA NEGRELLI

Art Unit

3733

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-18 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/11/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichtman (U.S. Patent No. 5,308,357).

As to **claims 15 and 18**, Lichtman discloses an instrument (see Fig.7) for gripping a tibial keel component of a modular keel and tray assembly, the keel component having a first end and a second end, the keel component being configured for insertion of the second end into a tibial bone, the instrument comprising:

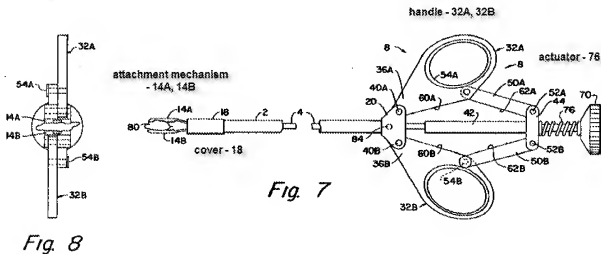
a handle (32A, 32B); an attachment mechanism (14A, 14B) for connecting the instrument to the keel such that the handle extends outwardly from the keel component to provide a grip for manipulating the keel component (see Fig.7); and a cover, the cover (18), with the keel component connected to the instrument, selectively positionable over a portion of the keel component to shield the portion of the keel component from contamination (see Fig.7).

As to **claim 12**, Lichtman further discloses wherein attachment mechanism (14A, 14B) connects the instrument to the keel component in a reproducible known orientation such that the orientation of the handle indicates the orientation of the keel component even when the keel component is not itself visible (col.6, ll.30-40) (see Fig.7).

As to **claim 13**, Lichtman further discloses wherein the attachment mechanism (14A, 14B) further comprises: a first jaw (14A) attached to the handle; and a second jaw (14B) attached to the handle, the jaws being movable relative to one another to clamp the keel component (see Fig.7).

As to **claim 14**, Lichtman further discloses wherein the attachment mechanism further comprises: an actuator (76); a link connecting the actuator to the jaws, the actuator being movable to cause the jaws to move between a closed position in which they are relatively close together and an open position in which they are relatively further apart, the actuator, link, and jaws having a point of singularity beyond which further movement of the actuator results in the jaws locking onto the keel in the closed position (col.7, ll.60-68, and col.8, ll.1-20) (see Figs. 1, 7, 9, 10).

As to **claims 16 and 17**, Lichtman further discloses wherein the cover (18) is movable while the instrument is connected to the keel component between a first position in which the cover is positioned over the portion of the keel component and a second position in which the cover is positioned away from the portion of the keel component to expose the keel component and wherein the cover is lockable in both the first and second positions (see Figs. 1, 7, 9, 10).



Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Robie et al. (U.S. Patent No. 6,159,217).

As to **claim 30**, Robie discloses a tibial keel holder and tibial tray holder combination, the tibial keel holder being engageable with a tibial keel component of a

modular tibial implant and the tibial tray holder being engageable with a tibial tray component of a modular tibial implant, the tibial keel component and tibial tray component forming a male/female junction between them, the combination comprising: a tibial keel holder including a first handle (see Fig.12: element - 100), a clamp (see Fig.1: elements – 20, 30) for connecting the tibial keel holder to the tibial keel component in a reproducible known orientation, and a cover, the cover, with the keel component connected to the tibial keel holder, selectively positionable over a portion of the keel component to shield the portion of the keel component from contamination; and a tibial tray holder including a second handle and an attachment mechanism for connecting the tibial tray holder to the tibial tray component in a reproducible known orientation, the first and second handles forming a predetermined angle between them to give a visual indication of tray-to-keel rotational alignment (see Fig.12).

As to **claim 31**, Robie further discloses wherein the proper tray-to-keel alignment is indicated when the first and second handles are parallel to one another (see Fig.11).

As to **claim 32**, Robie further discloses an assembly tool for moving the tibial tray component and the tibial keel component into male/female seating arrangement, the assembly tool being engageable with the tibial tray component and the tibial keel component while the tibial tray holder is holding the tibial tray (col.6, ll.1-36).

Allowable Subject Matter

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 03/11/2009 have been fully considered but they are not persuasive.

The applicant argues that the shaft (2) and metal ferrule (18) of Lichtman are not selectively positionable over a portion of a keel component with the keel component connected to the instrument. Thus, claim 15, as well as claims 12-14 and 16-18 which depend therefrom, are not anticipated by Lichtman.

The examiner respectfully disagrees. Lichtman does disclose a shaft (2) that is capable of being selectively positionable over a portion of a keel component with the keel component connected to the instrument. Lichtman discloses leaves (Fig.17: element – 12A, 12B) that are long and thick enough to be resiliently flexible over the range of motion depicted in Figs. 1, 7, 9, and 10 and affect proper functioning of the jaw assembly. Figures 1, 7, 9, and 10 also demonstrate four different positions of the handle mechanism, thus affecting the range of motion of the jaw members (14A, 14B). Due to the force-limiting or force-compensating effect of spring (76), the jaws are able to hold a keel component in place (col.8, ll.46-68). The shaft (2) controls the jaw

members. Thus claim 15, as well as claims 12-14 and 16-18 which depend therefrom, are anticipated by Lichtman.

The applicant also argues that the components of Robie et al. of which the examiner calls to form a clamp fail to actually disclose a clamp. The components have been reassigned as noted in the rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA NEGRELLI whose telephone number is (571)270-7389. The examiner can normally be reached on Mon-Fri. 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. N./
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733